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EXAMINER	
RANGREJ, SHEETAL	

ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/787,045	HATLESTAD ET AL.	
	Examiner	Art Unit	
	Sheetal R. Rangrej	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/25/2004; 04/21/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Prosecution History Summary

- Claims 1-28 are pending.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 02/25/2004 and 06/08/2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "102", "104", "105", and "106" have all been used to designate "device" (figure 1); reference characters "236" (figure 2) and "248" (figure 4) have both been used to designate "operating system"; reference characters "214" (figure 2), "154" (figure 5) and "252" (figure 4) have all been used to designate "memory"; reference characters "240" (figure 2) and "254" (figure 4) have both been used to designate "program module"; reference characters "242" (figure 2) and "258" (figure 4) have both been used to designate "program data"; reference characters "244" (figure 2) and "246" (figure 4) have both been used to designate "input device"; reference characters "212" (figure 2) and "250" (figure 4) have both been used to designate "CPU"; reference characters "304", "306", "308", and "310" have all been used to designate "computer system" (figure 6); reference characters "316" (figure 6) and "320" (figure 6) have both been used to designate "database"; and reference characters "318" (figure 6) and "322" (figure 6) have both been used to designate "server computers". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid

abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "262" has been used to designate both "LED display" (figure 4) and "housing" (figure 3); reference character "105" has been used to designate both "device" (figure 1) and "medicine therapy management device" (figure 6). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 9-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Yarin et al. (U.S. Patent No. 6,294,999).

6. As per claim 9, Yarin teaches an electronic patient health management system, comprising:

-a medical measurement device for measuring data related to at least one patient physiological health factor **(Yarin: col. 5, 49-64)**;

-a medication therapy management device, configured to house medication and store data related to patient consumption of medication **(Yarin: col. 3, 37-40)**, the medication therapy management device further configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement[[s]] device and the data related to patient consumption of medication **(Yarin: col. 11, 5-10; col. 11, 34-47)**; and

-a patient wellness host system, communicatively coupled to the medication therapy management diagnostic device, configured to receive and display the processed data **(Yarin: col. 11, 20-23)**.

7. As per claim 10, Yarin teaches wherein the medication therapy management diagnostic device is further configured to provide a reminder to a patient when it is time to take the medication **(Yarin: col. 10, 63-64)**.

8. As per claim 11, Yarin teaches wherein the medical measurement device is a external measurement device **(Yarin: col. 11, col. 3, 51-65)**.

9. As per claim 12, Yarin teaches wherein the medical measurement device is an implantable device **(Yarin: col. 11, col. 3, 51-65)**. The examiner interprets that the invention does not change as a whole because data is communicated with a device; the invention as a whole doesn't change with the device being an external device or an implantable device.

10. As per claim 13, Yarin teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to the patient wellness host system via an Internet connection **(Yarin: col. 3, 41-50)**.

11. As per claim 14, Yarin teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to the patient wellness host system via a wireless communication link **(Yarin: col. 3, 41-50; col. 6, 3-5)**.

12. As per claim 15, Yarin teaches wherein data related to the at least one patient physiological health factor comprises fluid retention data **(Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44)**.

13. As per claim 16, Yarin teaches wherein data related to the at least one patient physiological health factor comprises data monitored by an implantable device **(Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44)**.

14. As per claim 17, Yarin teaches wherein data related to the at least one patient physiological health factor comprises weight data **(Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44)**.

15. As per claim 18, Yarin teaches wherein data related to the at least one patient physiological health factor comprises neuro-hormonal data **(Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44)**.

16. As per claim 19, Yarin teaches wherein data related to the at least one patient physiological health factor comprises renal function data **(Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44)**.

17. As per claim 20, Yarin teaches further configured to process said data received in order to develop and display a therapeutic response **(Yarin: col. 11, 11-26)**.

18. As per claim 21, Yarin teaches wherein the developed therapeutic response comprises revising medication regime **(Yarin: col. 11, 48-54)**, maintaining current medication regime **(Yarin: col. 3, 36-40)**, and recommending a diet plan **(Yarin: col. 11, 40-47)**.

19. As per claim 22, Yarin teaches wherein the patient wellness host system is a computer, which comprises with a memory **(Yarin: col. 7, 3-5)**, a processor **(Yarin: col. 6, 45-48)** and a user interface **(Yarin: col. 6, 26-28)**.

20. As per claim 23, Yarin teaches wherein the medication diagnostic device communicates with the patient wellness host system to alert the wellness manager that the medication level is below a pre-determined level **(Yarin: col. 5, 42-46)**.

21. As per claim 24, Yarin teaches a method for remote management of a medication therapy via utilizing a medication containment unit whereby the method comprises the following steps:

-alerting a patient when it is time to carry out a step of a first therapeutic plan **(Yarin: col. 10, 53-64)**;

-sensing when the medication containment unit is engaged and recording the same as a medication event **(Yarin: col. 9, 21-41; col. 11, 5-10)**;

-receiving patient physiological data **(Yarin: col. 5, 49-54)**;

-processing said patient physiological data and said medication event data **(Yarin: col. 11, 34-**

47); and

-generating a second therapeutic plan in response to said processing of said patient physiological data and said medication event data **(Yarin: col. 11, 34-47)**.

22. As per claim 25, Yarin teaches wherein the alerting step comprises notifying the patient consume at least one of the following, medication **(Yarin: col. 10, 53-64)**.

23. As per claim 26, Yarin teaches wherein the alerting step comprises causing the medication containment unit to generate one of the following, an audible sound, to vibrate and to communicate with a second external device which responsively prompts the patient to act **(Yarin: col. 8, 43-48)**.

24. As per claim 27, Yarin teaches wherein the receiving step is initiated by an external device transmitting patient physiological data to the containment unit **(Yarin: col. 5, 49-54)**.

25. As per claim 28, Yarin teaches wherein the receiving step is initiated when the containment unit interrogates an external device **(Yarin: col. 5, 49-54)**.

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

27. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warkentin et al (U.S. Patent No. 6,471,645) in view of Yarin et al (U.S. Patent No. 6,294,999).

28. As per claim 1, Warkentin teaches a medication storage, therapy and consumption management system, comprising: -a containment unit configured to accessibly house medication

(Warkentin: fig. 4A-4B; col. 10, 19-22); and -a health management host system coupled to the containment unit in a manner that allows data transmission **(Warkentin: col. 10, 30-43)**, wherein the containment unit includes a communications system **(Warkentin: fig. 5)**. Warkentin further teaches said health management host system configured to receive data related to the medication event **(Warkentin: col. 14, 16-23)**, receive patient physiological data, analyze and display the patient physiological data and the medical event data on a health management display **(Warkentin: col. 14, 11-14)**.

Warkentin does not teach a medication story, therapy and consumption management system that comprises a control system that records and transmits data relating to a medication event, said containment unit control system further providing for transmitting and receiving medication therapy data.

Yarin teaches a medication story, therapy and consumption management system that comprises a control system that records and transmits data relating to a medication event, said containment unit control system further providing for transmitting and receiving medication therapy data **(Yarin: fig. 8)**.

One of ordinary skill in the art at the time the invention was made would have found it obvious to combine the teachings of Warkentin with Yarin with the motivation that many patients are treated at home and unable to manage their treatments especially medication regimens, which requires various scheduling and dietary guidelines **(Yarin: col. 1, 18-28)**.

29. As per claim 2, Warkentin does not teach wherein the patient physiological data comprises weight, fluid retention data, data monitored by an implantable device and neuro-hormonal data.

Yarin teaches wherein the patient physiological data comprises weight, fluid retention data, data monitored by an implantable device and neuro-hormonal data **(Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44)**. The examiner interprets that measurements relating to weight, fluid retention data, data monitored by an implantable device, and neuro-hormonal data are included in the data gathered by various appliances.

The motivation to combine the teachings is the same as claim 1.

30. As per claim 3, Warkentin teaches wherein the containment unit is further configured to communicate wirelessly with said health management host system **(Warkentin: col. 10, 36-43)**.

31. As per claim 4, Warkentin does not teach wherein the containment unit is configured with a display device to illustrate a medication therapy strategy.

Yarin teaches wherein the containment unit is configured with a display device to illustrate a medication therapy strategy **(Yarin: fig. 12; col. 6, 29-35)**.

The motivation to combine the teachings is the same as claim 1.

32. As per claim 5, Warkentin does not teach wherein the containment unit is configured to receive data from an external source and further configured to transmit such data to the health management host system.

Yarin teaches wherein the containment unit is configured to receive data from an external source and further configured to transmit such data to the health management host system **(Yarin: col. 11, 28-33)**.

The motivation to combine the teachings is the same as claim 1.

33. As per claim 6, Warkentin does not teach wherein the containment unit is further configured to notify the patient when it is time to take the medication housed therein.

Yarin teaches wherein the containment unit is further configured to notify the patient when it is time to take the medication housed therein **(Yarin: col. 10, 63-64)**.

The motivation to combine the teachings is the same as claim 1.

34. As per claim 7, Warkentin does not teach wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level

Yarin teaches wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level **(Yarin: col. 3, 41-50)**.

The motivation to combine the teachings is the same as claim 1.

35. As per claim 8, Warkentin does not teach wherein said health management host system processes said data related to the medication event data and said patient physiological data, and in response thereto provides for the generation of an updated medication therapy regimen.

Yarin teaches wherein said health management host system processes said data related to the medication event data and said patient physiological data, and in response thereto provides for the generation of an updated medication therapy regimen **(Yarin: col. 11, 11-26)**.

The motivation to combine the teachings is the same as claim 1.

Conclusion

36. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

-Ellinwood, Jr. (U.S. Patent No. 3,923,060) discloses an apparatus for dispensing drugs through an implanted device over a long period of time.

-Aten et al. (U.S. Patent No. 4,674,652) discloses a drug dispensing device that is controlled for the patient for a drug therapy.

-Shepherd et al. (U.S. Patent No. 4,911,327) discloses a dispenser for providing scheduled dosages of pills according to a predetermined medication program.

-Fearnot (U.S. Patent No. 5,040,533) discloses an implantable container for housing a cardiovascular treatment device with an external window for sensing a physiological parameter.

-Drinan et al. (U.S. Publication No. 2003/0004403) discloses an invention that relates to methods and devices for remote or distributed continuous monitoring physiological parameters.

-Kehr et al. (U.S. Publication No. 2003/0036683) discloses a method and an apparatus used in remotely modifying medical protocols.

-Mann et al. (U.S. Publication No. 2004/0147969) discloses an apparatus for treating cardiovascular disease with an implantable device.

-Surwit et al. (U.S. Patent No. 6,980,958) discloses an apparatus configured to receive and analyze information regarding patient compliance with medication and alter treatment regimens based on that information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheetal R. Rangrej whose telephone number is 571-270-1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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